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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,886	10/31/2003	Tetsuo Tsuji	0032-0284P	9003

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EXAMINER	
WOODWARD, CHERIE MICHELLE	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/697,886	TSUJI ET AL.	
	Examiner	Art Unit	
	Cherie M. Woodward	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

1. Applicant's Response and Amendments, filed 29 June 2006, are acknowledged. Claims 1-8 are pending and under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

Claim Objections/Rejections Withdrawn

Objections to Title and Minor Informalities in Claims

2. Applicant's arguments, filed 29 June 2006, with respect to the objection to the title and the claim objections for minor informalities have been fully considered and are withdrawn in light of Applicant's amendments.

Obviousness-Type Double Patenting

3. The rejection of claims 1-8 on the ground of nonstatutory obviousness type double patenting over claims 7-11 and 17-19 of US patent 6,677,124 is withdrawn for the following reasons:

Applicant argues that Applicant was prevented from presenting the claims corresponding to those of the instant application during the prosecution of Application 09/942,709, now US Patent 6,677,124.

Upon review of the prosecution history in the parent case 09/942,709, it is noted that a restriction election was required. The two groups established by the Examiner were comprised of Group I (claims 1-6 and 21), drawn to a method of producing a monoclonal antibody and a monoclonal antibody that specifically binds an epitope presented by the amino acid sequence SEQ ID NO: 2, classified in class 424, subclass 139.1 and Group II (claims 7-20 and 22-27), drawn to an immunoassay for the human natriuretic peptide, hBNP and kits comprising same, classified in class 436, subclass 512. Applicant traversed the rejection. Examination proceeded with the election of Group I. However, it appears from the record that the Group I was recharacterized as being drawn to a product of a monoclonal antibody. Once it was determined that Group I contained allowable subject matter, the claims of Group II were rejoined with the claims of Group. However, the Examiner stated that because claims 16-20, 23, and 25 were not directed to the process of making or using the patentable product, claims 16-20, 23, and 25 will not be rejoined. The Examiner never withdrew the restriction requirement. Applicant's representative gave approval for the cancellation of claims 16-20, 23, and 25 in the parent case by Examiner's Amendment. Because the

restriction requirement in the parent case was not withdrawn prior to allowance, the obviousness-type double patenting rejection made in the Office Action of 29 June 2006, is withdrawn.

Applicant's argument regarding the belief that the examiner cannot require a terminal disclaimer in the case unless the presently claim subject matter diverges from that originally filed, is not accurate, but is moot in light of the Examiner's withdrawal of the obviousness-type double patenting rejection. For clarification, Applicant is referred to MPEP 804.

Claim Rejections - 35 USC § 112, Second Paragraph

4. The rejection of claims 3-5 and 7, which recite the limitation "said first (or second) antibody", for having insufficient antecedent basis is withdrawn in light of Applicant's amendments.

5. The rejection of claim 2, recites the limitation "said Fab' fragment", which appears to refer to an epitope, for having insufficient antecedent basis for this limitation in the claim, is withdrawn in light of Applicant's amendment.

Claim Rejections - 35 USC § 112, First Paragraph, Scope of Enablement

6. The rejection of claims 1-3 and 6-8 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a first monoclonal antibody and a second antibody that is polyclonal or monoclonal, does not reasonably provide enablement for a first antibody that is polyclonal or monoclonal and a second antibody that is monoclonal or polyclonal, is withdrawn for the reasons below.

Applicant argues that the specification provides support for a first polyclonal or monoclonal antibody and supports the generic language with regard to recognition of different regions of hBNP. Applicant recognizes on page 9 (last sentence of third paragraph) of Applicant's Remarks that the first antibody could be a polyclonal antibody. Applicant also argues that the specification does not limit the region of hBNP that the second antibody recognizes. Further, Applicant submits that the invention will work as presently claimed. Applicant's argument has been fully considered and are persuasive because of what is known in the art.

Contrary to Applicant's argument and reference to page 6, lines 1-7 of the specification, which specifically recites "the above-mentioned monoclonal antibody A and an antibody B"... then goes on to recite a preferred embodiment, the Examiner has not been able to locate any recitation in the specification that discloses the use of two polyclonal antibodies. However, it is well known in the art that a sandwich

assay comprising two polyclonal antibodies will work, albeit not as efficiently as an assay comprising at least one monoclonal antibody. Because immunoassays using polyclonals against hBNP are known in the art and it would be considered routine experimentation to immunize an animal with purified hBNP in order to elicit a polyclonal immune response against the hBNP antigen, the claims are enabled by the art, and the rejection is withdrawn.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description

7. The rejection of claims 1-3 and 6-8 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn for the reasons below.

Applicant combined the Responses to the scope of enablement and written description rejections, even though *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1115 (Fed. Cir. 1991), makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision. In the combined response, Applicant argues that the specification provides support for a first polyclonal or monoclonal antibody and supports the generic language with regard to recognition of different regions of hBNP. Applicant recognizes on page 9 (last sentence of third paragraph) of Applicant's Remarks that the first antibody could be a polyclonal antibody. Applicant also argues that the claims are fully enabled as written. Applicant's argument has been fully considered and are persuasive because of what is known in the art.

Because polyclonal antiserum is known to be comprised of a multiplicity of individual monoclonal antibodies and because Applicant's would have had to have been in possession of polyclonal producing B-cells in order to produce a hybridoma capable of making the monoclonal antibodies disclosed in the specification, the Examiner believes the Applicant was in possession of polyclonal antibodies at the time the instant invention was made. As such, the rejection is withdrawn.

Claim Objections/Rejections Maintained

Claim Rejections - 35 USC § 103

8. The rejection of claims 1,2, 6, and 8 under 35 U.S.C. 103(a) as being unpatentable over Itoh et al., (Endocrinology, 1990 Sep;127(3):1292-1300) in view of Takeyama et al., (1990 Jul 3;130(2):217-22), Sutcliffe et al., (1983 Feb 11;219(4585):660-6), Harlow et al., (Antibodies, A Laboratory Manual. 1988. Cold Spring Harbor Laboratory. pp 578-582), Hashida et al., (Clinica Chimica Acta 1988 175:11-1), and

Bulinski (Intl Rev Cytology 1986;103:281-302) are maintained for the reasons of record and for the reasons set forth herein.

Claims 1, 6, and 8 recite an immunoassay using two antibodies which recognize two different regions of hBNP, with one region being the C-terminal region (amino acids 27-32 of hBNP). Claim 2 recites the immunoassay of claim 1 wherein the Fab' fragment of an antibody which is reactive with the first region of hBNP recognizes the intramolecular disulfide bridged loop structure of hBNP.

Applicant argues that Itoh et al., merely discloses the production of monoclonal antibodies to hBNP, and that Hashida et al., does not anticipate the immunoassay of the present invention because the instant invention is directed to a sample that is contacted with an immobilized antibody after it has been contacted with two different kinds of antibodies. Applicant also argues that teachings of Sutcliffe et al., Takeyama et al., Harlow et al., and Bulinski do not render the present invention obvious. Applicant also argues that each and every limitation of the instant claims are not taught or anticipated by the recited references and that there is no motivation to combine. Applicant's arguments have been fully considered but they are not persuasive.

The instant immunoassay, claimed by Applicant, combines two standard, well-known immunoassay techniques to quantify hBNP from a sample of biological fluid. The first part consists of a straightforward sandwich immunoassay, similar to the ones taught by Sutcliffe et al., Harlow et al., and Bulinski (all previously cited in the Office Action of 29 March 2006), in which a labeled Fab' fragment, reactive with the N-terminal of hBNP, is added to a sample of biological fluid along with an unlabeled antibody reactive with the C-terminal of hBNP. The labeled Fab' fragment and unlabeled antibody bind to different regions of the 32 amino acid long mature hBNP, thereby forming an immune complex, or sandwich, with the antigen (hBNP). The solution containing the sandwich complex is then brought into contact with an immobilized antibody that is designed to capture the Fc region of the unlabeled, bound antibody of the sandwich-antigen complex. In this way, the instant immunoassay combines a standard sandwich assay with an antibody capture technique.

Sutcliffe et al., Harlow et al., and Bulinski were cited to show that it was routine to make and screen for monoclonal antibodies exhibiting the desired specificity at the time the invention was made. Hashida et al., was cited to show that the use of an enzyme immunoassay for α-human atrial natriuretic polypeptide was well known in the art prior to the filing of the instant invention. α-human atrial natriuretic is a 28 amino acid polypeptide strikingly similar to the 32 amino acid peptide of human BNP. Itoh et al., teach comparisons of BNP and ANP (see Itoh, et al., p. 1292). In the absence of evidence to the contrary or in the absence of unexpected results, the production of antibodies having desired

specificity to BNP, as taught by Itoh et al., and Takeyama et al., and their use in immunoassays would have been *prima facie* obvious to one of ordinary skill in the art.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, Takeyama et al., teach the amino acid sequence of human BNP (p. 218, Figure 1) and that the amino acid sequence of BNP has a high sequence homology with atrial natriuretic peptide (ANP) (p. 218). Itoh et al., teach the production of monoclonal antibodies to BNP for use in radioimmunoassays (p. 1293, column 1) including a monoclonal antibody that recognizes the intramolecular disulfide bridged loop of human BNP (identified as the "ring structure of hBNP" on p. 6, first paragraph) of hBNP (see p. 1294, column 2, fourth paragraph, and Figure 1). Hashida et al., teach an enzyme immunoassay for α-human atrial natriuretic polypeptide by using polystyrene balls coated with monoclonal IgG specific for the N-terminal half of the disulfide bond ring structure of α-hANP and rabbit Fab' specific for the C-terminal (17-28) of α-hANP, which were conjugated to horseradish peroxidase, in which the sample was first added to the immobilized antibody (p. 12, Introduction). Although the specific sandwich assay of Hashida et al., varies slightly in that the sample was added to the immobilized antibody at the outset, it would have been obvious to the person of ordinary skill in the art at the time the instant invention was made (especially in light of the well-known antibody sandwich assay protocols and modifications taught by Sutcliffe et al., Harlow et al., and Bulinski) to first create the antibody-antigen sandwich complex and then contact the immobilized antibody with the antibody-antigen sandwich complex.

Further, although the assay method would have been less efficient, polyclonal antiserum to hBNP was known in the art and it would have been obvious to one of ordinary skill in the art at the time the invention was made to use hBNP as taught by Takeyama et al., to produce monoclonal antibodies specific for BNP, as taught by Itoh et al., because Takeyama et al., taught that the amino acid sequence of hBNP is known, and Itoh et al., provides an expectation of success by demonstrating that BNP is antigenic. It would have also been obvious to produce monoclonal antibodies that are reactive with the C-terminal portion of hBNP because Sutcliffe et al., taught that peptide immunogens can be used for eliciting reagents with predetermined specificity that can be used for basic research and Bulinski teaches that the use of peptide antibodies are simple and well established. Thus, the C-terminal portion of hBNP could

have been used as the immunogen to produce antibodies specific for the C-terminal region of hBNP. Alternatively, one could have screened for the antibodies specific for the C-terminal region of hBNP because such screening methods are well known in the art and the use of even small peptides of 6-10 amino acids in length (as taught by Hashida), as immunogens, was simple and well established (as taught by Bulinski).

With regard to motivation, it was known in the art at the time the invention was made that increased BNP had been reported in the early phases of and following acute myocardial infarction. It was also known that BNP was involved in hypertension (see, for exemplary purposes only, Mukoyama et al., Biochem Biophys Res Commun. 1991 Oct 15; 180(1):431-6, Abstract only; Forssmann et al., Arch Histol Cytol. 1989; 52 Suppl:293-315, Abstract only; Kida et al., Rinsho Byori, 1989 Aug; 37(8):875-82, Abstract only). A person of ordinary skill in the art would have been motivated to make an immunoassay comprising BNP as an early diagnostic of acute myocardial infarction. Moreover, Itoh et al., specifically state that mAbs against BNP are useful tools to investigate the pathophysiological significance of BNP (p. 1299, first column, last paragraph).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

New Claim Rejections

Claim Rejections - 35 USC § 103

9. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Itoh et al., (Endocrinology, 1990 Sep;127(3):1292-1300, previously cited in the Office Action of 29 March 2006) and Takeyama et al., (1990 Jul 3;130(2):217-22, previously cited in the Office Action of 29 March 2006), in view of Bunting, US Patent 4,271,140 (2 June 1981), in further view of Mukoyama et al., (Biochem Biophys Res Commun. 1991 Oct 15; 180(1):431-6, Abstract only), Forssmann et al., (Arch Histol Cytol. 1989; 52 Suppl:293-315, Abstract only), Kida et al., (Rinsho Byori, 1989 Aug; 37(8):875-82, Abstract only), Harlow et al., (Antibodies, A Laboratory Manual. 1988. Cold Spring Harbor Laboratory. pp 92, 141-142, 148, 578-582, previously cited in the Office Action of 29 March 2006), and Hashida et al.,

(Clinica Chimica Acta 1988 175:11-1, previously cited in the Office Action of 29 March 2006). The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The instant immunoassay, claimed by Applicant, combines two standard, well-known immunoassay techniques to quantify hBNP from a sample of biological fluid. The first part consists of a straightforward sandwich immunoassay in which a labeled Fab' fragment, reactive with the N-terminal of hBNP, is added to a sample of biological fluid along with an unlabeled antibody reactive with the C-terminal of hBNP. The labeled Fab' fragment and unlabeled antibody bind to different regions of the 32 amino acid long mature hBNP, thereby forming an immune complex, or sandwich, with the antigen (hBNP). The solution containing the sandwich complex is then brought into contact with an immobilized antibody that is designed to capture the Fc region of the unlabeled, bound antibody of the sandwich-antigen complex. In this way, the instant immunoassay combines a standard sandwich assay with an antibody capture technique. The combination is known in the art as a double layer modification. See, Bunting, US Patent 4,271,140 (2 June 1981, especially column 2 to column 3).

It was known in the art at the time the invention was made that the mature form of human BNP is made up of 32 amino acids with a 17 amino acid ring closed by a disulfide bond between two cysteine residues, an amino-terminal tail of 9 amino acids, and a carboxyl-terminal tail of 6 amino acids. Mature rat and porcine BNP are also made up of 32 amino acids with strikingly similar homology (see Takeyama et al., previously cited in the Office Action of 29 March 2006, especially p. 218, Figure 1, which compares the amino acid sequences of the 32 amino acid BNP of the three species). Takeyama et al., also teach polyclonal antisera against porcine BNP for use in microenzyme immunoassays (p. 218, column 2, first full paragraph).

Itoh et al., teach the production of monoclonal antibodies to BNP for use in radioimmunoassays (previously cited in the Office Action of 29 March 2006, p. 1293, column 1) including a monoclonal antibody that recognizes the intramolecular disulfide bridged loop of human BNP (identified as the "ring structure of hBNP" on p. 6, first paragraph) of hBNP (see p. 1294, column 2, fourth paragraph, and Figure 1). The monoclonal antibodies of Itoh et al., were derived from rabbit and mouse polyclonal antisera against BNP (p 1292, column 2, last paragraph to p. 1293, first paragraph). The use of monoclonal antibodies to in an immunoassay is well known and routine in the art (see, for exemplary purposes only, Sutcliffe et al., Harlow et al., and Bulinski, previously cited in the Office Action of 29 March 2006, and *supra*). Moreover, Itoh et al., specifically state that mAbs against BNP are useful tools to investigate the pathophysiological significance of BNP (p. 1299, first column, last paragraph).

Hashida et al., teach an enzyme immunoassay for α-human atrial natriuretic polypeptide (a 28 amino acid polypeptide). In this assay, polystyrene balls were coated with monoclonal IgG specific for the N-terminal half of the disulfide bond ring structure of α-hANP and rabbit Fab' specific for the C-terminal (17-28) of α-hANP was conjugated to horseradish peroxidase, in which the sample was first added to the immobilized antibody (p. 12, Introduction). Hashida et al., also teach that the C-terminal half of α-hANP was raised in rabbits by immunization with α-hANP (17-28)-bovine thyroglobulin conjugate (p. 13).

Applicant has previously clarified that the antibodies of the instant immunoassay can be monoclonal or polyclonal. Applicant will appreciate that polyclonal antibodies are compositions of a multiplicity of monoclonal antibodies, each specific to a particular antigenic epitope. It is well established that individual B-cells produce antibodies to only one antigenic epitope and that once programmed, a B-cell can only make antibodies to against the programmed epitope. Because a full complement of B-cells are involved in eliciting a cellular immune response to an antigen via immunization, for example, antibodies against many different antigenic epitopes will be produced by the numerous B-cells involved in the cellular immune response. Monoclonal antibodies are isolated by fusing the multiplicity of B-cells with myelomas (usually) to immortalize them, thereby creating hybridomas. A screening process takes place that permits identification of particular hybridoma with particular antigenic epitopes (see Harlow et al., pp. 92, 141-142, and 148).

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to have elicited monoclonal antibodies to the N-terminal of hBNP because Itoh et al., teach that mAbs against BNP are useful tools to investigate the pathophysiological significance of BNP (p. 1299, first column, last paragraph) and Mukoyama et al., Forssmann et al., and Kida et al., showed increased hBNP in the early phases of and following acute myocardial infarction, as well as increases in expression in hypertensive disorders (see abstracts). A person of ordinary skill in the art would have been motivated to make an immunoassay using monoclonal antibodies comprising hBNP as an early diagnostic of acute myocardial infarction.

One would have been motivated to produce monoclonal antibodies specific for the C-terminal region of hBNP because Itoh et al., teach monoclonal antibodies specific for the N-terminal region of BNP, such as KY-BNP-II. Hashida et al., and Takeyama et al., provide an expectation of success by teaching that BNP has a high sequence homology with ANP. Thus, production of monoclonal antibodies specific for the C-terminal region of hBNP would allow one to perform sandwich immunoassays or modified sandwich immunoassays, which are one of the most useful and efficient immunoassays (see

Harlow et al., *supra*). Because it was routine to make and screen for monoclonal antibodies exhibiting the desired specificity at the time the invention was made, in the absence of evidence to the contrary or in the absence of unexpected results, the production of antibodies having desired specificity and their use in immunoassays would have been *prima facie* obvious to one of ordinary skill in the art.

Because hBNP was well known to be of clinical interest and was an excellent antigenic target for the production of antibodies to the C-terminal region of the 32 amino acid peptide, it would have been *prima facie* obvious to have generated monoclonal antibodies in order to provide a potentially unlimited source of homogenous reagent for uses such as affinity purification, functional studies, or clinical studies of the macromolecules using the techniques disclosed by Bunting (see, *i.e.*, column 2 to column 3). One would have reasonably expected success because Takeyama et al., teach that the structure hBNP is antigenic (p. 218, Figure 1) and binds antibodies elicited to a structurally similar macromolecule, ANP (p. 218). Additionally, Itoh et al., provide further motivation for the labeling and solid-phase immobilization of anti-hBNP monoclonal antibodies (p. 1293, column 1), including a monoclonal antibody that recognizes the intramolecular disulfide bridged loop of human BNP (identified as the "ring structure of hBNP" on p. 6, first paragraph) of hBNP (see p. 1294, column 2, fourth paragraph, and Figure 1), as well as the use of monoclonal antibodies against BNP in diagnostic assays.

Because the Office does not have the facilities to determine whether the antibodies produced by hybridoma KY-hBNP-II, FERM BP-2863 and hybridoma BC203, FERM BP-3513 can bind hBNP in a way that other monoclonal antibodies or polyclonal antiserum (which is comprised of a multiplicity of epitope-specific monoclonal antibodies) cannot, the burden is on the application to show a novel and unobvious difference between the claimed antibodies produced by hybridoma KY-hBNP-II, FERM BP-2863 and hybridoma BC203, FERM BP-3515 and that of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

Conclusion

NO CLAIM IS ALLOWED.

This action is non-final.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cherie M. Woodward whose telephone number is (571) 272-3329. The examiner can normally be reached on Monday - Thursday 9:00am-7:30pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CMW

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